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Comparison of two different grafts for the surgical treatment of peyronie's disease

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Abstract

The aim of this study was to compare two different graft techniques, namely saphenous vein (SV) and buccal mucosa (BM) used together with plaque incision for the treatment of Peyronie's disease (PD) in terms of success, safety and patient and partner satisfaction. The study included 41 patients diagnosed with PD and treated with plaque incision and grafting between December 2015 and November 2019. Eighteen patients underwent plaque incision and BM grafting while the remaining 23 patients underwent plaque incision and SV grafting. Pre-operative plaque size, curvature angle, curvature start time and penis length were statistically similar between the SV and BM graft groups. No statistical difference was detected between the BM and SV graft groups in terms of the sixth- and 12th-month mean International Index of Erectile Function scores, Patient Global Impression of Improvement scores, penis lengths and final partner satisfaction rates during the follow-up period. Residual curvature was observed in three (13.1%) patients in the SV graft group and two (11.2%) patients in the BM graft group. With their high success and low side effect rates, both grafting techniques with plaque incision can be safely performed for tunical lengthening, based on the surgeon's experience.

KEYWORDS

buccal mucosa, graft techniques, peyronie's disease, saphenous vein

1 | INTRODUCTION

Peyronie's disease (PD) is defined as a penile deformity (curvature, hourglass deformity, shortening) created by an acquired palpable plaque formed by the fibrotic structure on the tunica albuginea layer of the penis (Hatzichristodoulou, 2016; Hellstrom, 2003). The most common reason for PD patients to present to hospital is difficulty with sexual intercourse due to this deformity, which may be accompanied by pain during erection (Hatzichristodoulou, 2016). The incidence of PD is 0.4%–9% in males, and it is most commonly observed in the sixth decade (Mulhall et al., 2004). Conservative, medical and surgical treatments are among the treatment options for PD (Levine & Burnett, 2013). Surgery, which is the main treatment option for PD, aims to correct the deformity while preserving penile erection function and penis length (Zucchi et al., 2015). Surgery is a suitable option for stable patients that developed this deformity at the least 12 months earlier and report no pain during erection for the last three months (Lentz & Carson, 2009). The surgical decision is generally made based on curvature localisation, degree, penis length, deformity type and erection status (Cormio et al., 2019; Kadioglu et al., 2008). Among current treatment options are reconstructive techniques such as shortening of the convex side with simple corporoplasty, lengthening of the concave side with a partial plaque incision/excision and grafting methods, and penile prosthesis implantation in patients with erectile dysfunction (ED) (Cormio et al., 2019; Hatzichristodoulou, 2016). Different graft techniques

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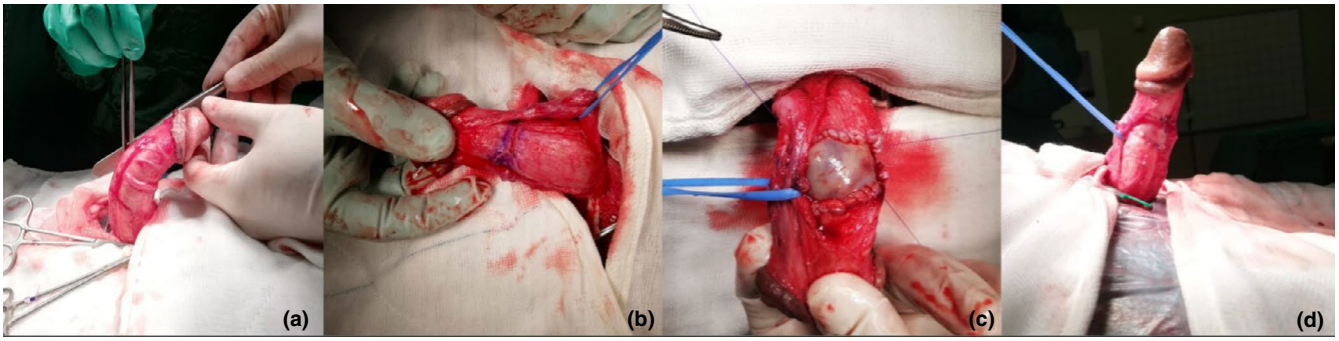

FIGURE 1 Surgical Steps of BM grafting group. (a) Deformation of penis by artificial erection after degloving. (b) Appearance of penis and Y-shape incision after mobilisation of the neurovascular bundle. (c) Buccal mucosal patch sutured to the defect. (d) Results of the correction by artificial erection

have been used since the first use of adipose tissue for grafting in 1950 (Lowsley & Boyce, 1950). Lengthening procedures have the highest success rate in patients with severe deformities and shortened penises (Cormio et al., 2019). Grafts are divided into four groups as autografts, allografts, xenografts and synthetic grafts. Today, autografts are commonly preferred for their characteristics such as minimal aneurysmatic dilatation risk, easy suturability and manipulability, flexibility, ability to ensure the continuity of the veno-occlusive function of the tunica albuginea, and minimal infection risk, but they can also cause increased morbidity due to harvesting (Carson & Chun, 2002; Fabiani et al., 2016). Autografts currently used for this purpose include the saphenous vein (SV), dermis, buccal mucosa (BM), rectus fascia, fascia lata and tunica albuginea (Fabiani et al., 2016; Hatzichristodoulou, 2016). The SV graft provides elasticity with the muscle layer and elastic fibrins it contains, and thus it is the most commonly preferred autograft (Cormio et al., 2009). The BM graft, which has been commonly preferred in recent years, also presents as a safe and reproducible method with excellent short- and medium-term results (Cormio et al., 2019; Levine & Burnett, 2013). The literature contains various clinical studies presenting the results of SV and BM grafting separately, but to date, neither has been reported to be perfect (Levine & Burnett, 2013).

The aim of this study was to compare these two different graft techniques (SV and BM) performed together with a plaque incision in terms of their success, safety and patient and partner satisfaction. To the best of our knowledge, this is the first study in the literature to perform the comparison of the grafting techniques in the same patient cohort.

2 | PATIENTS AND METHODS

After obtaining approval from the institutional review board (2020–253), the study was carried out with 41 patients with PD, who underwent plaque incision and grafting from December 2015 to November 2019. Clinical data were retrospectively obtained from the prospectively-populated database of two university hospitals. The inclusion criteria comprised a disease duration of at least 12 months, stable disease presentation for a minimum of three months, difficulty or impossibility of intercourse due to penile deviation, and an age of 18 years or above. The exclusion criteria were current penile pain, hourglass deformity and ED that is refractory to phoshodiesterasetype-5 (PDE-5) inhibitors or intracavernous injections (ICI) [10 mg prostaglandin E1 (PGE1])]. All the patients were fully informed of the aim of the study and signed a detailed informed consent form. The pre-operative evaluation included a detailed medical and sexual history, a physical examination, penile Doppler ultrasound after ICI, measurement of the angle and direction of curvature using two rigid rulers, and measurement of the length of the affected side from the penile basis to the urethral meatus in a state of full erection. The erectile function of the patients was evaluated with the Turkish version of the International Index of Erectile Function (IIEF-5). The potency of the patients was questioned both preoperatively and postoperatively and defined as an IIEF-5 score of ≥ 17 (Turunç et al., 2007). During the follow-up stage, the Patient Global Impression of Improvement (PGI-I) questionnaire was used to identify the changes in the patients' condition, and their partners were directed questions to elicit their subjective opinion on sexual activity (excellent, satisfied or poor) to evaluate their satisfaction (Viktrup et al., 2012). Penile rigidity, straightness and length were evaluated based on the IIEF-5 scores and the ICI test (Mulhall et al., 2007; Viktrup et al., 2012). In the PGI-I questionnaire, the patient is asked to best describe his condition compared to before he underwent surgery. The patient responds on a seven-point scale (1: very much better; 2: much better; 3: a little better; 4: no change; 5: a little worse; 6: much worse; and 7: very much worse) (Zucchi et al., 2015). Anatomic success was defined as the complete straightening of the curvature or residual curvature of less than 20°. Follow-up visits were scheduled at the post-operative first, third, sixth and 12 months, and yearly thereafter.

3 | SURGICAL TECHNIQUES

The penis skin was degloved with a circumcising incision under general anaesthesia. Buck's fascia was incised through the dorsal of penis following degloving, and the neurovascular bundle and urethra were carefully dissected to provide satisfactory exposure. Either

medial or lateral dissection was preferred, depending on the plaque location. Following the induction of an artificial erection, the length of the affected side was measured, and the site of maximal curvature was incised, extending the ends to a double-Y shape.

In the group in which BM grafting was to be performed after the plaque incision, a graft as large as possible was taken from inside the left cheek for harvesting according to the plaque size. Oral cavity and face were prepared with 0.4% chlorhexidine antiseptic solution before harvesting. The graft was cleaned of superficial muscular tissues, adapted to the dimensions and form of the tunica albuginea defect, placed longitudinally with its submucosal surface on the corpus cavernosum, and sutured along its circumference with continuous 2–0 Vicryl (Ethicon, LLC, Somerville, NJ, USA) (Figure 1). The patch was incised longitudinally in the middle by 1–2 cm in order to ensure sufficient drainage in case of a possible haematoma under the patch (Shioshvili & Kakonashvili, 2005). In the SV grafting group, a similar exposure was provided for the plaque by repeating the procedures described above. Then, as described by Lue et al., the tunical defect size was measured, and the harvested SV graft was placed with its endothelial site facing the cavernosal tissue using 4–0 polydioxanone (PDS, Ethicon Inc., NJ) sutures (Figure 2) (Lue & El-Sakka, 1998). The results of the correction were documented intraoperatively by repeatedly inducing artificial erection using physiological saline. In case of residual curvature (greater than 20°) after artificial erection, additional single or paired plication sutures were applied depending on the surgeon's preference. Finally, Buck's fascia was carefully closed, a Foley catheter was inserted, and a slightly compressive penile dressing was placed. The two individual methods were applied by two different experienced surgeons (B.E. and A.S.).

In the BM graft group, mouth washing with 0.4% chlorhexidine solution was continued until the post-operative fifth day. Antibiotic prophylaxis was performed with third-generation cephalosporin in both groups and continued until the 48th hour, postoperatively. The Foley catheters and penile dressings of the patients in both groups were removed on the post-operative first day, and the patients were discharged on the post-operative first or second day. The patients were allowed to continue to have sexual intercourse 30 days after the operation.

3.1 | Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences version 21 (IBM SPSS Statistics; IBM Corp., Armonk, NY, USA). The Shapiro–Wilk test was used to determine whether the distributions of continuous variables were normal. Mean differences between two related groups of normally distributed data were compared using an independent *t*-test, while the Mann–Whitney *U* test was used to compare nonnormally distributed data. The frequencies of categorical variables were compared using Pearson's chi-square or Fisher's exact test, where appropriate. Statistical significance was considered when the *p* value was less than .05.

4 | RESULTS

Eighteen patients underwent plaque incision with BM grafting and 23 patients underwent plaque incision with SV grafting. All patients had positive responses to the ICI test before surgery. According to the evaluation of plaque localisation, six (33.3%) patients had dorsal, seven (38.8%) patients had ventral, and five (27.7%) patients had lateral localisation in the SV graft group whereas in the BM graft group, eight (34.7%) patients had dorsal, six (26%) patients had ventral and nine (39.1%) patients had lateral localisation ($p = .635$). The mean curvature angle of the patients was 70 ± 12.2° in the SV graft group and 75 ± 10.4° in the BM graft group ($p = .554$). The SV and BM graft groups were statistically similar in terms of the pre-operative plaque size and curvature starting time ($p = .250$; $p = .507$, respectively). The mean pre-operative penis length was calculated as 11.89 ± 0.9 cm in the SV graft group and 11.92 ± 0.8 cm in the BM graft group ($p = .790$). The mean operation duration was 132.8 ± 29.9 min in the SV graft group and 116.8 ± 26 min in the BM graft group, and there was no statistical difference between the two groups ($p = .586$). Additional small tunical plication stitches were needed to obtain complete penile straightening in five (21.7%) patients from the SV graft group and four (22.2%) patients from the BM graft group ($p = .630$). There were no intraoperative complications. Pain was observed in the leg donor site of one (4.3%) patient from the SV graft

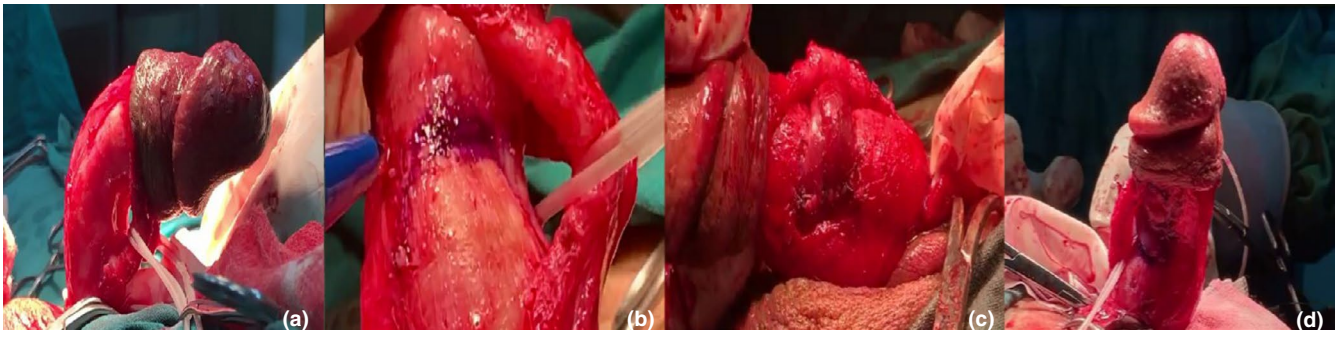

FIGURE 2 Surgical Steps of SV grafting group. (a) Deformation of penis by artificial erection after degloving. (b) Appearance of incision after mobilisation of the neurovascular bundle. (c) Venous patch sutured to the defect. (d) Results of the correction by artificial erection

group and ecchymosis was observed in the penile shaft of one (5.5%) patient from the BM graft group as a post-operative complication, and both regressed with conservative treatment during the follow-up. Postoperatively, glans hypoesthesia was present in two (8.6%) patients from the SV graft group and one (6.25%) patient from the BM graft group (p = .702). The mean length of hospital stay was similar between the two groups (1.63 ± 0.51 days for the SV graft group versus 1.67 ± 0.51 days for the BM graft group; p = .952). The pre-operative and operative features of the patients are presented in Table 1. The mean follow-up period was 18 ± 4.8 months in the SV graft group and 17.7 ± 3.9 months in the BM graft group (p = .270). No statistical difference was detected between the BM and SV graft groups in relation to the mean IIEF-5 scores and penis lengths at the sixth and 12th months of the follow-up period (p > .05). De novo ED occurred in three (13.1%) patients from the SV graft group and three (16.6%) patients from the BM graft group during the post-operative period (p = .744). All these patients were given 5 mg tadalafil daily to support more successful intercourse.

No statistical difference was detected between the groups in terms of the patients' PGI-I scores or final partner satisfaction at the sixth and 12th months (p = .909 and p = .553, respectively). Residual curvature was observed in three (13.1%) patients in the SV graft group and two (11.2%) patients in the BM graft group (p = .619). Additional intervention was not considered for these patients since they had no problems with sexual intercourse. Anatomic success was achieved in 20 (86.9%) patients in the SV graft group and 16 (88.8%) patients in the BM graft group (p = .619). The comparison of the post-operative results is shown in Table 2.

TABLE 1 Pre-operative and operative features of the patients

Data	SVG (n:23)	BMG (n:18)	p[a]
Age (years)	57.65 ± 6.4	53.17 ± 10.1	.027
BMI (kg/m^2)	28.1 ± 4.05	26.3 ± 3.9	.854
Degree of the curvature^0	70 ± 12.2	75 ± 10.4	.554[b]
Medical treatment period (month)	9.8 ± 3.6	8.9 ± 2.3	.621
Duration of disease (month)	21.8 ± 5	20.2 ± 5.5	.507
Site of curvature; n (%)			
Dorsal	8 (34.7)	6 (33.3)	.635[c]
Ventral	6 (26)	7 (38.8)	
Lateral	9 (39.1)	5 (27.7)	
Length of affected side (cm)	11.8 ± 0.9	11.9 ± 0.8	.790
Pre-operative IIEF−5 score	19.2 ± 2.7	18.9 ± 2.6	.567
Plaque size (mm^2)	300.8 ± 86.6	313.6 ± 117.3	.250
Duration of surgery (min)	132.8 ± 29.9	116.8 ± 26	.586
No. of patients with plication; n (%)	5 (21.7)	4 (22.2)	.630[d]
Hospitalization time (day)	1.63 ± 0.51	1.67 ± 0.5	.952[b]

Abbreviations: BMG, Buccal mucosa grafting; BMI, Body mass index; IIEF-5, International Index of Erectile Function; SVG, Saphenous vein graft.

[a]Independent-Samples t-test.

[b]Mann Whitney U test.

[c]Pearson Chi-square.

[d]Pearson Chi-square Exact test.

5 | DISCUSSION

Tunical lengthening procedures are preferred in PD patients who have a complex curvature of over 60°, an hourglass curvature, and a short penis (Hatzimouratidis et al., 2012; Kadioglu et al., 2008). Total plaque excision can also be applied to the affected tunica albuginea layer in tunical lengthening procedures but this method is not used or recommended today due to its high post-operative ED risk. Modified H-shaped or Y-shaped plaque incision is currently recommended (Hatzichristodoulou, 2016). In our cohort, we preferred Y-shaped plaque incision before both grafting methods. Grafting techniques are more complex than plication. Extensive dissection and the extraction of the neurovascular bundle with Buck's fascia may pose a post-operative risk of ED development (Hatzichristodoulou, 2016). Thus, for an ideal graft, harvesting should be easy and not prolong the operation, and it should be cost-effective, infection-resistant and safely removable, cause no contracture, and help recover erectile capacity (Carson & Chun, 2002; Hatzichristodoulou, 2016).

Vein grafts have higher adaptability since they have a muscular layer and elastic fibrins, and they can be fed through cavernosal blood flow as they have thin vascular wall layers and are more physiological (Chang et al., 2002).

In addition to these advantages, today, SV grafting has become the most commonly used method due to the low possibility of post-operative scar, de novo ED and foreign body reaction, its increased compliance over time, and its differentiation to tunica albuginea (Cormio et al., 2019; Kadioglu et al., 2008). Integration time is four to six weeks with the use of inert implant materials; for example, pericardium, porcine small intestine submucosa and porcine derma, and this can cause more reactive scar formation compared with living materials such as BM. BM grafts cause very little scar formation due to their high cavernosal tissue inosculation and revascularization capacity (Cormio et al., 2019; Zucchi et al., 2015). In studies in the literature, success in PD surgery is generally defined as the elimination of curvature in the early post-operative period and maintenance of erectile capacity (Kadioglu et al., 2008).

SV grafting provides good functional and anatomical results with 10%–50% ED and 66.6%–96.6% success ratios (Kim et al., 2008; Kim et al., 2008; Lue & El-Sakka, 1998; Yurkanin et al., 2001). For BM grafting, the success ratio has been reported as 87.5%–100%, and the post-operative ED ratio as 0%–7.7% (Chang et al., 2002; Cormio et al., 2009; Shioshvili & Kakonashvili, 2005). In our study, the success rate was determined as 86.9% in the patients who underwent

TABLE 2 Comparison of post-operative results after use of saphenous vein (SV) and buccal mucosa (BM)

Data	SVG (n:23)	BMG (n:18)	p^a
Follow-up duration (months)	18 ± 4.8	17.7 ± 3.9	.270
Post-operative IIEF−5 score			
6-month IEEF	17.7 ± 3.4	17.4 ± 4.2	.504[b]
12-month IEEF	19.8 ± 3.5	20.5 ± 1.7	.559[b]
Length of affected side (cm)			
6-month	13.5 ± 0.8	13.6 ± 0.7	.488
12-month	13.5 ± 0.7	13.7 ± 0.6	.702
Penile straightening; *n* (%)	20 (86.9)	16 (88.8)	.619[c]
Residual curvature; *n* (%)	3 (13.1)	2 (11.2)	.619[d]
Glans hypoesthesia; *n* (%)	2 (8.6)	1 (6.25)	.702[d]
De nova ED; *n* (%)	3 (13.1)	3 (16.6)	.744[d]
PGI-I score			
6-month	1.7 ± 1.1	2.1 ± 1.1	.909[b]
12-month	1.7 ± 0.8	1.5 ± 0.8	.553[b]
Partner satisfaction rate; *n* (%)	20 (86.9)	16 (88.8)	.619[c]
Anatomic success rate; *n* (%)	20 (86.9)	16 (88.8)	.619[c]

Abbreviation: BMG, Buccal mucosa grafting; IIEF-5, International Index of Erectile Function; PGI-I, Patient Global Impression of Improvement; SVG, Saphenous vein graft.

[a]Independent-Samples *t*-test.

[b]Mann–Whitney *U* test.

[c]Pearson Chi-square.

[d]Pearson Chi-square Exact test.

SV grafting and 88.8% in those who underwent BM grafting. The rates of post-operative de novo ED in the SV and BM graft groups were 13.1% and 16.6%, respectively. It was also observed that there was an increase of 0.62 and 1.56 points in the mean IIEF scores of the SV and BM graft groups, respectively. All these results were statistically similar between the two patient groups.

SV grafts, which tend to vascularize through the 1/3 section of the wall, have very little perfusion possibility from the endothelium. For this reason, grafts that cannot be vascularised properly carry a higher probability of recurrence and shortening of the penis during the short-term and long-term follow-up. Yurkanin et al. detected no penis shortening with SV grafting and an increase of 0.5–5 cm in penile length after vacuum device expansion during the post-operative period (Yurkanin et al., 2001). Cormio et al. (2009) reported that all patients who underwent BM grafting achieved penile straightening, and there was a mean increase of 1.8 cm in penis length. In our study, while none of the patients had penile shortening, there was a mean increase of 1.62 cm in post-operative penile length on the affected side in the SV graft group, and a mean increase of 1.8 cm in the BM graft group. In a mean follow-up of 41.7 months of patients that had undergone plaque incision and SV grafting, Kadioglu et al. reported a residual curvature of 20° or more in 11.4% of patients and 100% patient satisfaction (Kadioglu et al., 2008). In a study by Cormio et al. (2009) for the plaque incision and BM grafting group, the patient and partner satisfaction rates were 93.3% and 100%, respectively. In our study, the residual curvature rate was determined as 13.1% in the SV group and 11.2% in the BM group. In the literature, the curvature site has also been shown as a risk factor for residual curvature. In particular, higher rates of residual curvature have been reported in patients with lateral curvatures, and it had been recommended that graft techniques should be avoided in these patients (Kadioglu et al., 2008; Usta et al., 2003). Hsu et al. hypothesised that a higher rate of residual curvature in patients with lateral curvatures was associated with susceptibility of the lateral tunica at 3- and 9-o'clock positions to trauma, potentially resulting in the breakdown of the graft site (Hsu et al., 1994). Considering this hypothesis, we did not expect a difference between the two groups in our study. Therefore, also considering this reason and the small number of patients in the subgroups, we did not perform such comparison.

In addition to evaluating the surgical success and satisfaction of the patients, we also assessed the partner satisfaction rates, unlike many studies in the literature. In our study, the post-operative sixth- and 12th-month PGI-I scores and partner satisfaction rates were statistically similar between the patients in the SV and BM graft groups.

Harvesting is easy for BM grafts, and complications (numbness and tension in the mouth and Stensen's duct injury) rarely occur at the donor site (Zaid et al., 2014). BM harvesting appears safer than other grafts since infection and immunological response are low and biocompatibility is high (Cormio et al., 2009). In our study, no harvesting-related complications were observed in any of the patients that underwent BM grafting. In both graft techniques, only one patient in each group experienced a complication but did not require any additional intervention other than conservative treatment. Some surgeons perform additional supportive interventions such as PDE-5 inhibitors and use a vacuum device to provide post-operative penile straightening, but neither a PDE-5 inhibitor nor a vacuum device was used in our patients other than those with de novo ED (Levine et al., 2005). The duration of operation was reported to be longer for SV grafting due to the differences in harvesting procedures (Zucchi et al., 2015). However, in our study, since both types of harvesting were performed by different operation teams and experienced surgeons applied both methods, there was no statistically significant difference between the two graft techniques despite the longer operation time in the SV graft group.

In the literature, there is not yet any consensus on the ideal graft due to the different follow-up times and heterogenous samples, as well as the limited numbers of patients (Cormio et al., 2019). This study showed that both grafting techniques, which are commonly preferred to other types of autologous grafts, could be safely used with similar long-term success rates.

Our study has certain limitations. In our study, we only reported the sixth- and 12th-month follow-up results due to the lack of data

for the 18th-month follow-up. However, this is a common limitation, with most previous studies reporting the results of a very short follow-up and some only reporting the results of the final evaluation. In addition, we did not evaluate cost analysis for both surgical techniques since they were performed by two different surgical teams. However, since biocompatible materials and 'stretching therapy' with a vacuum device were not used in either method, we believe that the cost of the two techniques would have been similar. As another limitation, although the IIEF-5 score is frequently used to evaluate sexual function in men with PD, it has never been specifically validated for use in this disease, and a more specific test such as Peyronie's Disease Questionnaire could have provided more precise results. Lastly, more objective results could be obtained with a penile Doppler ultrasonography.

6 | CONCLUSION

There is still no recommendation for the ideal graft type. Surgeon experience, patient selection, penile deformity type, deformity severity and economic considerations all influence graft selection. In tunical lengthening, plaque incision with the SV or BM grafting technique offers high success and low side effect rates due to the suitable tissue elasticity and adaptability of these grafts. Although our results are promising, the risks and benefits of these grafting options must be weighed by considering each individual case, and long-term prospective, randomized studies with higher numbers of patients are warranted to further investigate these treatment methods.

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None.

CONFLICT OF INTEREST

The authors declare no conflict of interest regarding this study.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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